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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,951	08/22/2003	Scott T. Wepfer	CPC-10003/22	8257

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EXAMINER

SOROUGH, LAYLA

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,951	Applicant(s) WEPFER, SCOTT T.	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,20 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,20 and 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed March 13, 2006 presents remarks and arguments submitted to the office action mailed December 15, 2006 is acknowledged.

Applicant's amendments submitted February 28, 2007 is acknowledged wherein claims 1-18, 21-23 are canceled, 19-20, 24 are amended and claims 25-30 are added.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of Claims 19-21 and 24 over Mantelle (US Pat. No. 5,446,070) in view of Pomerantz (US Pat. No. 5,081,157) is persuasive due to amendments made to claims. Therefore, the rejection is herewith withdrawn.

Claims 19-20 and 24-30 are pending.

In view of Applicant's cancellation, amendments, and addition of new claims the following new rejections are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20, 24, 26, 27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mantelle (US Pat. No. 5,446,070).

The invention herein reads on a method of reducing pain sensation comprising applying a therapeutically effective amount of an anhydrous gel anesthetic formulation consisting of in an anhydrous mixture at least one anesthetic compound selected from

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the group consisting of procaine, lidocaine, and tetracaine, a skin penetration enhancer, hydroxypropylcellulose (a gelling agent) with an optional ingredient selected from the group consisting of preservative, fragrance, buffer, and an emollient; and an optional therapeutic agent is selected from the group consisting of: analgesics, anxiolytic compounds, antiarrhythmics, antibacterials, antibiotics, anticoagulants, anticonvulsants, antifungals, antihistamines, antiinflammatories antivirals, bronchodilators, calcium channel blockers, cytotoxics, and anticancer agents, cytokines, growth factors, immunosuppressives, muscle relaxants, psychotherapeutics, sympathomimetics, vasodilators, and vitamins.

Mantelle teaches a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 25 the ointment composition consists of lecithin (emollient), propylene glycol (skin penetration enhancer), isocetyl alcohol (emollient), glycerin (preservative), lidocaine base, tetracaine HCL (analgesic), and hydroxypropyl cellulose Klucel, HF (gelling agent),(column 20).

Mantelle teaches a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 16 the composition consists of karaya gum (buffer), lecithin (emollient), propylene glycol (skin penetration enhancer), diproylene glycol (volatile solvent), glycerin (preservative), benzyl alcohol (skin penetration enhancer), and lidocaine base.(column 18).

Mantelle teaches a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 28 the ointment

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composition consists of lecithin (emollient), propylene glycol (skin penetration enhancer) in 44 w/w%, glycerin (preservative), Klucel, HF (gelling agent), lidocaine base, and tetracaine HCL (analgesic), (column 21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (US Pat. No. 5,446,070) in view of Swinehart (US Pat. No. 5961997).

Mantelle is as discussed above.

Mantelle fails to exemplify the composition claimed wherein lidocaine is present from 0.5-6 total weight percent or an anti-itch agent.

Mantelle teaches the anesthetic agents can comprise about 1 to about 50% by weight of the total composition, hence rendering the claimed limitations obvious (col 5, lines 50-60).

Additionally, Mantelle teaches antipruritics as ingredients in the pharmaceutical compositions (col 34 lines 10-15), hence meeting the limitation of claim 28.

Swinehart teaches a topical composition comprising lidocaine and an anti-pruritic.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Mantelle composition by routine experimentation (see MPEP 2144.05 11) and use an anti-itch agent because Mantelle teaches (1) the suitable dose range (2) that antipruritics are suitable for such compositions and Swinehart teaches (3) a topical composition comprising lidocaine and an anti-pruritic. The motivation to optimize the dose range of Mantelle's final formulation is because one would have had reasonable expectation of success in achieving the safest clinical outcome.

Response to Arguments

Applicant's arguments filed March 13, 2007 have been considered.

Applicant argues claim 19 excludes a salt of an anesthetic base, a binder, and anesthetic base in the form of prilocaine, a drug in the form of miconazole nitrate, a corticosteroid, an adregnocosticosteroid, or a keratolytic agent. Firstly, Examiner directs Applicant's attention to the new rejection made over claim 19 which is directed only to Examples 25 and 28 of the Mantelle teachings. Secondly, Examples 25 and 28 of the prior art teaches a free base of lidocaine as claimed herein. The anesthetic agent salt still falls within the claimed invention because of the additional limitation drawn to any analgesic.

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR

1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

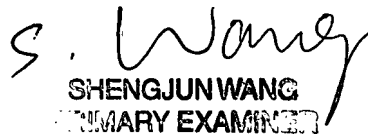
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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


SHENGJUN WANG
PRIMARY EXAMINER